NOV 2 6 2003

K032087

"510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Keeler Instruments Inc.
456 Parkway
Broomall, PA. 19008

Contact Person & Telephone: Eugene R. VanArsdale
(610)-353-4350

Date Summary Prepared: July 2, 2003

Device Name: Classification Name – Indirect Ophthalmoscope
Common/Usual Name- Ophthalmoscope
Proprietary Name – Keeler Wide Angle Ophthalmoscope

Predicate Device: Welch Allyn 11800 Ophthalmoscope

Device Description, Intended Use & Effectiveness:

The Keeler Wide Angle Ophthalmoscope is a hand held indirect monocular device for use by trained personnel for viewing the cornea and retina of a patient. The viewing path in conjunction with the large solid angle projection of the illumination path provides two angles of view which provides larger fields of view than attainable with a conventional direct ophthalmoscope. The viewing optical system composes of two objective lenses, relay components and eyepiece provide an erect, un-reversed image of the patients retina to the doctor.

The illumination path of the instrument consists of a filament lamp, a condensing system, two full mirrors and one semi-reflector mirror. The illumination path is imaged just below the viewing optics axis as they combine at the semi-reflector mirror. The condensing lenses image the lamp filament essentially onto the patient's cornea. The filament image at the corneal plane is small permitting an increase ease of entry into un-dilated pupil.

Any reflections of the filament from the surface of the cornea are trapped on light stops, which are positioned within the viewing optics. This allows the practitioner to obtain reflex free images of the retina.

This instrument with it two larger field of views and increased ease of entry allows for a more thorough examination of the retina while minimizing the exam and exposure time to the patient. The effectiveness of the Keeler Wide Angle Ophthalmoscope is the same as current monocular indirect ophthalmoscopes already on the market.

Technological Characteristics:

Criteria	Keeler Wide Angle Ophthalmoscope Model No: 1130-P-5004
Type:	Monocular Indirect
Power Source:	3.5 volts
Illumination:	Xenon lamp
Viewing Optics:	Glass
Image Position:	Right Side Up
Size:	190mmL x 120mmH, x 45mmW
Weight	300 grams
Date Introduced	2003

Safety: An abundance of safety areas were investigated and reviewed from the Risk Analysis stage, right through the project to ensure that the Keeler Wide Angle Ophthalmoscope is as safe as or safer than existing similar devices already in the market place. The specific safety areas considered are as follows:

Toxicity - Materials used are neither toxic nor known to create significant allergic reactions when used as intended by the manufacturer.

Electrical - External test house approval to EN ISO 15004

Light - Light output levels are consistent to similar devices in the field, UV and IR filtering complies with EN ISO-15004.

Corrosion - Device is non-corrosive

Explosion - Highly unlikely; manufactured of non-explosive materials. Uses approved medical grade power supplies already on the market.

Surface - Temperature All surfaces have been evaluated for practitioner and patient contact.

Fire Hazard - Probability extremely low. This system is illuminated by a xenon lamp, which draws a maximum of 2.6 watts of power.

Mechanical - The instrument has been designed to ensure that the risk of physical injury when performing the intended function(s) has been reduced as much is practicable.

Design - Product Risk Assessment to EN1441, Risk Analysis, Verification and validation were conducted on this device.

Summary of Effectiveness:

The determination of device effectiveness was co-coordinated in the following manner.

The Keeler Wide Angle Ophthalmoscope development teams conducted assessments of the device with practicing physicians in an effort to establish if the device met all of the practitioner's needs.

The evaluating physicians were also users of either the Keeler Ophthalmoscope or a competitor's model (all have the same intended use). The results of the assessments indicated that the Keeler Wide Angle Ophthalmoscope performs the needs of the documentation procedure in an equivalent or better manner of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Keeler Instruments Inc.
% Mr. Eugene R. VanArsdale
Marketing Manager
456 Parkway
Broomall, PA 19008-4295

Re: K032087
Trade/Device Name: Keeler Wide Angle Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: October 20, 2003
Received: October 21, 2003

Dear Mr. VanArsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use:

Applicant: Keeler Instruments Inc.

510(k) Number (if known): K032087

Device Name: Keeler Wide Angle Ophthalmoscope

Indications for Use:

The Keeler Wide Angle Ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution. The device is intended to be used by trained personnel within a medical or school environment.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K032087